ISRCTN98523729 https://doi.org/10.1186/ISRCTN98523729

Comparison of auditory and visual training for adult cochlear implant users

Submission date
14/09/2017

Recruitment status
No longer recruiting

Registration date
20/09/2017

Overall study status
Completed

Last Edited
01/10/2021

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Auditory training effects on speech recognition are inconsistent amongst adult cochlear implant users. Identifying the specific aspects of "listening" that are being targeted by training may further the understanding of this variance. Additionally, factors such as how individual characteristics interact with training outcomes and if training-induced changes influence social engagement and quality of life for hearing impaired individuals need to be addressed. This may enable us to customise rehabilitation options for cochlear implant users. The aim of this study is to compare whether auditory-verbal training leads to greater changes than visual-verbal training on short- and long-term, trained and untrained measures of listening and cognitive abilities in adult CI users.

Who can participate?
Adults aged 18 and older with over one year of cochlear implant experience.

What does the study involve?
Participants are randomly assigned to one of two groups. Individuals in both groups undertake two computer-based training programs at home: an auditory training and a visual training, however each group receives these in a different order. Participants are asked to undertake each training program for approximately 15 minutes per day, five days weekly for six weeks. Participants are assessed seven times throughout the study to assess for changes in auditory and cognitive abilities as well as self-perceived listening and quality of life.

What are the possible benefits and risks of participating?
Participants may benefit from the training programs in this study by experiencing improvement in their listening abilities. Participants may find the testing sessions tiring and may present psychological distress, such as frustration and anxiety, during training and assessment tasks.

Where is the study run from?
This study is being run from Macquarie University (Australia) and takes place in 3 centres: Macquarie University, Fiona Stanley Hospital, the HEARing Cooperative Research Centre (Australia).

When is study starting and how long is it expected to run for?
January 2015 to July 2018

Who is funding the study?
The HEARing Cooperative Research Centre and Macquarie University (Australia)

Who is the main contact?
Dr Mariana Reis
marianacpdosreis@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Mariana Reis

ORCID ID
http://orcid.org/0000-0003-3066-2331

Contact details
Room G.330, Ground Floor
16 University Avenue
The Australian Hearing Hub
Macquarie University
Sydney
Australia
2109

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
XR3.3.4(1)

Study information

Scientific Title
Comparison of computer-based auditory and non-auditory training for adult cochlear implant recipients

Study objectives
Research question:
Does computer-based auditory-verbal training lead to greater changes than visual-verbal

training on short- and long-term, trained and untrained measures of listening abilities in adult cochlear implant users?

Hypothesis:
Verbal-based training leads to greater changes in trained and untrained measures of listening abilities when presented in the auditory mode compared to the visual mode, and these changes are maintained weeks after the training is completed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Macquarie University Human Research Ethics Committee, 01/04/2015, ref: Protocol number: 201500069
The Royal Victorian Eye and Ear Hospital Human Research Ethics Committee, 17/05/2017, ref: Protocol number: 17/1327H

Study design
Multicentre randomised crossover design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Hearing loss, adult cochlear implant users

Interventions
As participants enrolled in the study, they received participant identification codes in chronological order and were allocated to a treatment order according to that specified for their code in a randomisation list pre-generated through www.randomization.com. All participants undertake six weeks of auditory training and six weeks of visual training. The order in which participants receive each intervention is randomised.

Participants are asked to use each programme once a day, five times per week during six weeks across all study sites (a total of 30 sessions). Training is individual, computer-based and takes place in the participants' home. Software interface and protocol for both programs were developed so their looks of and interaction needs were as similar as possible.

At the beginning of each training session, participants are asked to log how many hours they slept in the previous night as well as how they were feeling at the moment of the session (a five-point Likert scale from with smileys ranging from “very happy” to “very sad”), which are also saved to the sessions’ results.

The auditory training consists of monosyllabic words and sentences spoken by a female and male speaker with background babble noise used as a masker. The visual training consists of monosyllabic words and sentences written on the screen with a series of vertical bars masking the text. Each training program session consists of a module of 25 sentences and two modules of 25 monosyllabic words (divided by initial and final consonants). Participants are asked to identify the word/sentence that they heard/seen.

Difficulty for both programs is modulated by an adaptive protocol. That is, for each three stimuli correctly identified, the level of the masker (noise level or width of the vertical bars) is increased. If there is one incorrect answer, the level of masker difficulty would decrease (level of noise/width of bars). All tasks are closed-set, where participants are given three different alternatives to choose from. Feedback is provided whether a response is correct or incorrect. When a response is incorrect, participants are presented with the option they chosen as well as the correct option for that trial.

At the end of each module participants are informed the number of trials correctly identified.

The programs have administrator features, which enables study investigators to track participants’ results as well as allowing users to have access to only one program, both or any.

After completing 30 sessions participants are prevented from assessing the training program and are asked to attend a follow-up session at the investigation site. Following this, a three-month wash out period takes place for the first site (Macquarie University), whereas at the two other sites (HEARing Cooperative Research Centre and Fiona Stanley Hospital) the wash out period is one month.

Participants return to the investigational site for assessment after the wash out period twice before receiving the second training program.

Intervention Type
Behavioural

Primary outcome measure
Speech recognition scores are assessed through BKB sentences at fixed signal to noise ratios (SNRs) and consonant-nucleus-consonant (CNC) words at seven timepoints:
1. Before training 1 (baseline 1)
2. 1-2 weeks after timepoint 1 (baseline 2)
3. After receiving training 1 (effect of training 1)
4. 1-3 months after timepoint 3 (retention of effects of training 1)*
5. 1-2 weeks after timepoint 4 (baseline without training period for training 2)
6. After training 2 (effect of training 2)
7. 1-3 months after training 2 (retention of effects of training 2)*

*For recruitment and testing logistics, the retention period at the first site was set at 3 months, but shortened to 1 month for the other 2 sites.

Secondary outcome measures

1. Behavioural measures of spectral resolution is measured using spectral-temporally modulated ripple test
2. Visual and auditory attention is measured using integrated visual auditory continuous performance test
3. Sustained attention and inhibition control measured using Victoria Stroop test
4. Working memory is measured using reading span test
5. Speed of processing is measured using Victoria Stroop, letter monitoring and semantic judgement tests
6. Phonological representations is measured using rhyme judgement test
7. Speech hearing, spatial hearing, qualities of hearing, and listening effort is measured using the SSQ12 questionnaire
8. Confidence in management of communication situations in simple and complex noisy environments is measured using the SESMQ questionnaire
9. Communication apprehension across four communication contexts: public, small groups, meetings and interpersonal encounters is PRCA-24 questionnaire
10. Functional health and well-being is measured using SF-36 questionnaire
11. Quality of life aspects of Quality of Life scale

The above are measured at seven timepoints:
1. Before training 1 (baseline 1)
2. 1-2 weeks after timepoint 1 (baseline 2)
3. After receiving training 1 (effect of training 1)
4. 1-3 months after timepoint 3 (retention of effects of training 1)*
5. 1-2 weeks after timepoint 4 (baseline without training period for training 2)
6. After training 2 (effect of training 2)
7. 1-3 months after training 2 (retention of effects of training 2)*

*For recruitment and testing logistics, the retention period at the first site was set at 3 months, but shortened to 1 month for the other 2 sites.

Overall study start date
05/01/2015

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Adults aged 18 and older
2. Uni- or bilateral cochlear implant users
3. At least one year of cochlear implant experience
4. Competent English speakers
5. Able to use a computer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A power calculation, indicated a requirement of 18 participants in each active study group. This sample size implies a probability of 80% that the study will detect a treatment difference at a two-sided 0.05 significance level, if the true difference between treatments is 20% in Bamford-Kowal-Bench (BKB) sentences in noise.

Total final enrolment
26

Key exclusion criteria
1. Significant neurological or cognitive impairment
2. Significant visual impairment

Date of first enrolment
01/03/2016

Date of final enrolment
28/07/2017

Locations

Countries of recruitment
Australia

Study participating centre
Macquarie University
16 University Avenue
The Australian Hearing Hub
Macquarie University NSW
Sydney
Australia
2109

Study participating centre
Fiona Stanley Hospital
102 -118 Murdoch Drive
Audiology Service
Murdoch WA
Perth
Australia
6150

Study participating centre
HEARing Cooperative Research Centre
550 Swanston Street
Department of Audiology and Speech Pathology, University of Melbourne
Carlton VIC
Melbourne
Australia
3053

Sponsor information

Organisation
HEARing Cooperative Research Centre

Sponsor details
550 Swanston Street
Department of Audiology and Speech Pathology
The University of Melbourne
Carlton 3053 VIC
Australia
Melbourne
Australia
3053

Sponsor type
Research organisation

Website
www.hearingcrc.org

ROR
https://ror.org/01e5x8t10

Funder(s)

Funder type
Not defined

Funder Name
HEARing Cooperative Research Centre

Funder Name
Macquarie University

Alternative Name(s)
Universitas Macquariean, Macquarie University (Sydney, Australia), macquarieuni, Macquarie_Uni, Macquarie University | Sydney NSW, MQ

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Dissemination of results in local and international Audiology conferences.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/09/2021	01/10/2021	Yes	No